STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner

v **File No. 122073-001-SF**

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 19th day of December 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On June 27, 2011, XXXXX (Petitioner) filed a request with the Commissioner of Financial and Insurance Regulation for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. On July 5, 2011, after a preliminary review of the material submitted, the Commissioner accepted the request.

The Commissioner immediately notified Blue Cross Blue Shield of Michigan (BCBSM) of the request for external review and asked for the information it used to make its final adverse determination. The information was received on July 15, 2011.

Because it involved medical issues, the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations to the Commissioner on August 5, 2011.

II. FACTUAL BACKGROUND

The Petitioner's group health care benefits are defined in the *MESSA Choices Group Health Care Benefit Certificate* (the certificate). The plan is underwritten by BCBSM.

The Petitioner was diagnosed with sacroiliitis, an inflammation of the sacroiliac joint, and on August 7, 2009, she underwent pulsed radiofrequency ablation (PRA) as treatment for spinal pain. PRA uses radio frequency waves to produce heat on the nerves surrounding the spine. BCBSM denied coverage on the basis that PRA is investigational and therefore not a covered benefit under the certificate.

The Petitioner appealed BCBSM's denial. BCBSM held a managerial-level conference on April 20, 2011, and issued a final adverse determination dated May 16, 2011, upholding its denial. The Petitioner now seeks an external review of that decision.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's PRA procedure?

IV. ANALYSIS

In its final adverse determination, BCBSM advised the Petitioner:

> Our denial of payment for the Pulsed Radiofrequency Ablation (PRA) performed . . . on August 7, 2009 was correct because the procedure is considered investigational under the terms of your contract. Investigational procedures are not a benefit.
>
> . . . The term investigational/experimental is defined [*in the certificate*] in Section 1: The Language of Health Care as "A service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient's condition as conventional or standard care." In Section X: Exclusions and Limitations it explains that "services and supplies that are not medically necessary according to accepted standards of medical practice including any services which are experimental or investigational" . . . are an exclusion and/or limitation of your MESSA Choices program.
>
> . . . Our Joint Uniform Medical Policy (JUMP) Committee reviewed PRA performed for chronic spinal pain and determined it is investigational because PRA has not been scientifically demonstrated to be as safe and effective as conventional treatment.

BCBSM also based its denial on its medical policy entitled "Radiofrequency Ablation for Spinal Pain" which states:

> [T]he majority of patients do not experience complete pain relief, and the durability of the effects remains unclear due to a lack of prospective long-term follow-up data from randomized controlled trials. . . .

The Petitioner does not believe that PRA is experimental. She states she received additional PRA treatments after the procedure on August 7, 2009, and that BCBSM covered them. She is therefore seeking coverage for the August 7, 2009, service as well. BCBSM responded to the Petitioner's assertion in the final adverse determination:

> In regard to your other concerns, the related hospital claim for August 7, 2009 from XXXXX Hospital did not indicate that PRA was performed. Rather, the hospital billed for services related to a different, covered procedure. For that reason, the claim for the services provided by the hospital was approved and paid.
>
> In addition, I confirmed that the claims . . . for the services performed on November 29, 2009 and January 8 and June 10, 2010 also indicate that a different, covered procedure was performed.

The certificate excludes coverage for experimental services. The question of whether PRA was experimental or investigational for the treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is certified by the American Board of Anesthesiology with a subspecialty in Pain Management and is in active practice. The IRO report contained the following analysis and conclusion:

> This case involves a fifty two (52) year old female with sacroiliitis. Her sacroiliitis was diagnosed with steroid and local anesthetic sacroiliac (SI) joint injections. On August 7, 2009, she underwent a left sacroiliac joint radio frequency ablation via the medial branches at L5, S1, S2, and S3 left side. The ablations were performed without complication. She was discharged home in good condition.
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> The health plan has denied coverage on the basis that the Pulsed Radiofrequency Ablation performed on August 7, 2009 was considered experimental/ investigational.
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> **Reviewer's Decision and Principal Reasons for the Decision:**
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> It is the determination of this reviewer that the pulsed radiofrequency ablation was not experimental and is medically necessary for the LS and S 1 level.
>
> It is the determination of this reviewer that the pulsed radiofrequency ablation was experimental for the S2 and S3 level.
>
> **Clinical Rationale for the Decision:**
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> The radiofrequency ablations at L5 and S1 were medically necessary and supported by the literature. There is no literature to support medial branch radiofrequency ablations at S2 and S3. There is medical literature for lateral

branch radiofrequency ablations at S2 and S3. The two (2) separate types of injections will be discussed separately.

Prior to the patient's radiofrequency ablation, Bogduk, Levin, Burnham, and Manejias had all published that medial branch radiofrequency ablations are efficacious. In addition, Burnham published that this treatment actually decreases the cost of care. These studies included medial branch radiofrequency ablations down to the S1 level.

At S2 and S3, the standard ablation is lateral branch radiofrequency ablations. In two (2) separate papers Cohen has published that this treatment does not provide sufficient long-term pain relief. Therefore, lateral branch radiofrequency ablations are not medically necessary. There is no literature to support medial branch radiofrequency ablations at S2 and S3. Thus, treatment is experimental and therefore considered not medically necessary.

The enrollee was diagnosed with sacroiliitis by local anesthetic and steroid injections. She then underwent potentially curative treatment that is partially supported by the literature. According to the recent literature, the radiofrequency ablations should be completed at 80 degrees centigrade for 90 seconds with two (2) cycles completed at each level. In the note, there is no mention of pulsed radiofrequency ablations, so this reviewer cannot confirm that this enrollee, in fact, underwent pulsed radiofrequency ablations.

Since the medical literature supports medial branch radiofrequency ablations at L5 and S1, these treatments are medically necessary. Since there is no data to support medial branch radiofrequency ablations at S2 and S3, it is considered experimental and therefore, is not medically necessary. The medical literature currently does not support lateral branch blocks at S2 and S3.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the Pulsed Radiofrequency Ablation performed on August 7, 2009, be modified.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the IRO's recommendation and finds that the medial branch

PRA procedure at L5 and S1 on August 7, 2009, was not experimental. However, the medial branch radiofrequency ablation at S2 and S3 on that date was experimental and BCBSM is not required to cover it.

V. ORDER

Blue Cross Blue Shield of Michigan's final adverse determination of May 16, 2011, is reversed in part. BCBSM shall cover the medial branch radiofrequency ablation at L5 and S1 performed on August 7, 2009, within 60 days of the date of this Order. BCBSM shall, within seven (7) days of providing coverage, furnish the Commissioner proof it has implemented this Order.

BCBSM is not required to cover the medial branch radiofrequency ablation at S2 and S3.

To enforce this Order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free at (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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R. Kevin Clinton
Commissioner